IEMA
Illinois Emergency Management Agency
Division of Nuclear Safety

Rod R. Blagojevich, Governor
William C. Burke, Director

November 3, 2006

Dear Medical Use Licensee:

As we previously reported, on March 14, 2006, 32 Ill. Adm. Code Part 335 was approved by the Illinois State Legislature (effective date April 28, 2006). This rulemaking was implemented to ensure compatibility with U.S. Nuclear Regulatory Commission regulations and to ensure that the latest technologies were available to the medical community while also protecting patient and public health and safety. New requirements for medical events, written directives, use of dose calibrators, outpatient treatments, clinical trials of new products, approval for emerging medical technologies and use of gamma stereotactic radiosurgery were among those addressed in this rulemaking. Quality assurance for use of these technologies was also specifically addressed. The revised Part 335 can be obtained by accessing our website at http://www.state.il.us/iema/legal/regs/radmtl.asp.

Enclosed is a summary of the changes included in this rulemaking to facilitate the transition to the new requirements. We have also indicated which changes may require amendments to current radioactive materials licenses (underlined italics). Please be aware that these recommendations for amendment are not all-inclusive, and each Administrator/Radiation Safety Officer should review their programs to ensure compliance with these requirements. If the regulations conflict with the licensee's radiation safety program as identified in its license, the regulations shall apply, unless the statements, representations, conditions, and procedures in the license are more restrictive. However, if that licensee exercises its privilege to amend its license, the portion amended must comply with the requirements of the regulations. Applications for renewal and expedited renewal should also be reviewed thoroughly to ensure that your program is reflective of the new requirements.

In order to allow for the effective implementation of the new rules, the agency has determined a phased approach to inspection and enforcement of the revised rules is appropriate. Violations of those rules, which have become effective since April 28, 2006, will be noted to the licensee through April 28, 2007, when inspections are conducted. Noted items will not necessarily be cited as items of violation unless a substantially similar rule or license condition was in effect before the time of the rulemaking. It is our intent to bring new regulatory items to licensees' attention, allow them an opportunity understand the revised/new rule and to make program changes prior to the next routine inspection.

We appreciate your cooperation on this matter and hope that the new regulations facilitate the medical use of radioactive material while also protecting patient and public health and safety. If you have any questions, please feel free to contact Gibb Vinson for licensing concerns or Daren Perrero for enforcement issues (217) 785-9947.

Sincerely,

Joseph G. Klinger, Head
Radioactive Materials Section

Enclosure

32 IAC 335 – Medical Use of Radioactive Materials
SUMMARY OF REVISIONS

NRC	IEMA	Summary of Change
		SUBPART A: GENERAL INFORMATION
35.1	335.10	**Purpose and Scope** - Frivolous use language included
35.2	335.20	**Definitions** - Changes to definitions are self-explanatory. One definition of interest is patient intervention (used in 32 IAC 335.1080). In addition, Recordable and Reportable Events were deleted and replaced with 32 IAC 335.1080, Medical Events (See below).
35.11	335.30	**License Required** – Combined NRC's language in 10 CFR 35.49 and Illinois 32 IAC 335.1090. Deleted reagent kit language.
35.13	335.40	**License Amendments** – The Agency kept previous language here. Does not allow changes in personnel without approved amendments from the Agency.
35.40	335.50	**Written Directives** –Requirements still effective but moved to 32 IAC 335.1110.
35.6	335.60	**Provisions for Protection of Human Research Subjects** – This section confirms that 32 IAC 335 does apply to human research subjects and specifies requirements for such research including review and approval by an Institutional Review Board and informed consent of subject. *The licensee must seek an amendment if the research is not conducted, funded, supported, or regulated by a Federal Agency.*
		SUBPART B: GENERAL ADMINISTRATIVE REQUIREMENTS
20.1101	335.1010	**ALARA Program** –The ALARA Program was repealed. Now defer to 32 IAC 340.110 for this requirement. The meetings for this requirement may be used to meet the Radiation Safety Committee meetings below.
35.50 35.24	335.1020- 335-1040	**Radiation Safety Officer/Radiation Safety Committee** – 32 IAC 335.1020 and 32 IAC 335.1030 repealed. RSO and Radiation Safety Committee requirements now in 32 IAC 335.1040. Licensee and RSO must agree in writing about responsibilities of the Radiation Protection Program. They must also establish RSO authority and duties of the RSO in writing. RSO may also delegate certain duties under this section to other qualified individuals. Licensees with 2 or more types of use on the license must also establish Radiation Safety Committee. Meeting frequency has been deleted from this section, but the committee must meet at least annually to meet the requirements of 32 IAC 340.110. *Licensees may still commit to the appendices in Agency guidelines for RSO duties. If new RSO duties are developed, an amendment will be required.*

35.80	335.1070	**Mobile Nuclear Medicine Service Administrative Requirements** – These requirements are still effective but now appear in 32 IAC 335.2120.
35.3045	335.1080	**Report and Notification of Medical Event** – 'Recordable Events' and 'Reportable Events' have been replaced by 'Medical Events'. Medical events listed now are similar to Reportable Events with added criteria of a dose threshold. Under the previous rules reportable events were broken down by how the dose was administered and then the various specific errors (i.e. administration for therapy doses of I-131 in units of more than 30 microcuries with an error of 20%, gamma knife doses with an error of 10%, teletherapy doses varying by 10, 20 or 30% depending on the treatment method, brachytherapy doses with an error of 20% and radiopharmaceutical doses that exceeded 5 rem EDE or 50 rem to an organ.) Under the new rules, medical events are defined by a dose in excess of 5 rem EDE or dose to an organ of more than 50 rem being exceeded in conjunction with: (1) an error of more than 20% from the prescribed amount, (2) a dose outside the prescribed range, (3) use of a wrong drug, (4) use of the wrong route of administration, (5) the wrong patient, (6) the wrong treatment mode or (7) a leaking source. In all cases the actual dose to the patient or patient's organ must be determined. Patients and the referring physician must be notified within 24 hours of the discovery of the medical event.
35.49	335.1090	**Materials Authorized for Medical Use** – Combined into previous 32 IAC 335.30.
35.3047	335.1100	**Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child** – Required under Section 208 of the Energy reorganization Act by Congress. An unintended dose of 5 rem to an embryo/fetus and 5 rem to nursing child or any permanent functional damage to an organ or physiological system of the child must be reported. A 24-hour telephone notification to the Agency, a 15-day written notification to the Agency and a 24-hour notification to the referring physician and the patient are required.

35.40 35.41	335-1110- 335-1120	**Written Directives/Procedures for Administrations Requiring a Written Directive** – New section for Written Directives but requirements are the same. Written Directives required for higher risk administration (greater than 30 microcuries of I-131 or any therapy dose) to ensure that the radiopharmaceutical is administered as directed by the authorized user. This term is also used to differentiate between the term prescription, which may require less or different information than a Written Directive. 32 IAC 335.1120 was added to ensure identity of patient and doses are verified.
		SUBPART C: GENERAL TECHNICAL REQUIREMENTS
35.60	335.2010	**Possession, Use and Calibration of Instruments Used to Measure the Activity of Unsealed Radioactive Material** – The Agency allows licensees to perform linearity, accuracy, constancy and geometry for dose calibrators used to demonstrate compliance with the rules in accordance with manufacturer's/national standards. Licensees should be aware that possession of a dose calibrator is not required as long as an assay is made in accordance with 32 IAC 335.2030. However, the Agency recommends that a dose calibrator be used to confirm doses for quality control purposes. *This applies only to unsealed radioactive material. Manual brachytherapy sources are addressed in 32 IAC 335.7070. Licensees will need to amend licenses if they choose to eliminate dose calibrators from their program or to allow for alternate calibration methods.*
	335.2020	**Calibration of Survey Instruments** –These requirements are still effective but now in 32 IAC 340.540. Acceptable instruments are now specified in 32 IAC 335.2080.
35.63	335.2030	**Assay of Radiopharmaceutical Dosages** – New dose assay requirements. Unless a written directive is required, the licensee may make their own measurements of unit doses or use manufacturers or pharmacy assay, with decay correction. For doses requiring a written directive, direct measurement of the dose is required unless the dose involves beta emitters that the manufacturers/pharmacies are exclusively authorized to assay. If the unit dose is manipulated in any way, it must be assayed again before use. There are also volumetric/mathematical measurements allowed for multidose vials. Doses must fall within 20% of the prescribed dose or within a range specified by the authorized user.

35.65	335.2040	**Authorization for Calibration, Transmission, Attenuation Correction and Reference Sources** – Calibration, reference, transmission and attenuation sources addressed here. There is an increase to 30 mCi for approved sealed sources. Added Y-90 for Zevalin calibrations and Gd-153 for new attenuation correction sources up to 600 mCi. *Authorizations for certain calibration sources up to 30 mCi and most Gd-153 transmission sources can be removed from licenses as they are now covered by the regulation.*
35.67	335.2050	**Requirements for Possession of Sealed Sources** – Requirements for sealed sources including leak testing and inventories now in 32 IAC 340.410 and 32 IAC 340.810.
35.69	335.2060	**Labeling and use of Vials and Syringes** – The requirements for vials and syringes were combined into this section.
35.69	335.2070	**Vial Shields and Vial Shield Labels** – The requirements for vials and syringes were combined into 32 IAC 335.2060.
35.70	335.2080	**Monitoring for Contamination and Ambient Radiation Dose Rate** – The Agency kept most of the prescriptive language about types and frequencies of surveys. A footnote was added about type of instruments used for surveys (detection vs. measurement).
35.75	335.2090	**Safety Instructions for Patients Not Hospitalized and Containing Therapeutic Doses of Radiopharmaceuticals or Permanent Implants** – Repealed. Now have new 32 IAC 335.2110 for release of patients.
35.410 35.415	335.2100	**Admission of Patients Being Treated with Radiopharmaceuticals or Permanent Implants** – Repealed. Now have new 32 IAC 335.2110 for release of patients.

35.310 35.315	335.2110	**Release of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material** - New requirements for release of patients. *These requirements apply to patients that are undergoing studies requiring a written directive or any therapy procedure.* Licensees may release patients as long as the calculated total effective dose equivalent to any other individual does not exceed 500 mrem. If the dose is likely to exceed 100 mrem, the licensee must provide the primary care giver with verbal and written instructions to maintain doses ALARA. *Amendments are not necessary for this unless licensee has more restrictive procedures in the license application.* The licensee must evaluate and document releases as follows: a) The basis for authorizing the release of an individual to include the assessment and evaluation criteria for the patient's medical, living and working conditions, activities of radioactive material used (i.e., retained or administered activity), occupancy factors, biological or effective half-life of radioactive material, shielding by tissue, and means of estimating doses to any other individual and the physicians (NRC NUREG 1556, Vol. 9, Rev. 1, may be used to determine doses to individuals for patient releases). b) The instructions for each patient required by subsection (b) of this Section. c) The physician's certification for patient release required by subsection (c) of this Section. *Note: For diagnostic procedures requiring a written directive, an evaluation and written approval by the authorized user must be performed. However, for subsequent diagnostic studies using the same radiopharmaceutical/activity for patients with similar conditions, a simple reference to this initial assessment in the written directive will be acceptable.*
35.80	335.2120	**Mobile Nuclear Medicine Service** – Covers all mobile service requirements including those from former 32 IAC 335.1070.
N/A	335.2130	**Storage of Volatiles and Gases** – Precautions for storage and use of gases are now found in 32 IAC 340.820 and 32 IAC 340.830.
35.1000	335.2140	**Other Medical Uses of Radioactive Materials or Radiation from Radioactive Material (Emerging Technologies)** – New emerging technologies requirements are in this section. *Licensees must request an amendment prior to using radioactive material not specifically approved in Subparts D. through I.*

		SUBPART D: UNSEALED RADIOACTIVE MATERIAL FOR UPTAKE, DILUTION AND EXCRETION STUDIES – WRITTEN DIRECTIVE NOT REQUIRED
35.100	335.3010	**Use of Unsealed Radioactive Material for Uptake, Dilution or Excretion Studies for which a written directive is not required -** Requirements essentially the same as previous 32 IAC 335.3010. Doses must come from a licensed vendor, nuclear pharmacy, authorized physician or a licensee with a Radioactive Drug Research Committee approved protocol. *Notice that written directives also apply to diagnostic studies involving greater than 30 microcuries of I-131 and 32 IAC 335.5010 requirements would apply in those cases.*
		SUBPART E: UNSEALED RADIOACTIVE MATERIAL FOR IMAGING AND LOCALIZATION STUDIES FOR WHICH A WRITTEN DIRECTIVE IS NOT REQUIRED
35.200	335.4010	**Use of Unsealed Radioactive Material for Imaging and Localization Studies for Which a Written Directive is Not Required -** Requirements essentially the same as previous 32 IAC 335.4010. Doses must come from a licensed vendor, nuclear pharmacy, authorized physician or a licensee with a Radioactive Drug Research Committee approved protocol. *Notice that written directives also apply to diagnostic studies involving greater than 30 microcuries of I-131 and 32 IAC 335.5010 requirements would apply in those cases. If licensees authorized for diagnostic use only are administering I-131 with activities greater than 30 microcuries for diagnostic studies, their licenses will now have to be amended to include 32 IAC 335.5010 "for diagnostic studies only."*
N/A	335.4030	**Control of Aerosols and Gases** - Requirements still effective. Precautions for storage and use of gases are now found in 32 IAC 340.820 and 32 IAC 340.830.

		SUBPART F: UNSEALED RADIOACTIVE MATERIAL – WRITTEN DIRECTIVE REQUIRED
35.300	335.5010	**Use of Unsealed Radioactive Material for Which a Written Directive is Required** - Requirements essentially the same as previous 32 IAC 335.5010. Doses must come from a licensed vendor, nuclear pharmacy, authorized physician or a licensee with a Radioactive Drug Research Committee approved protocol. Notice that written directives may also apply to certain diagnostic studies involving I-131 and 32 IAC 335.5010 requirements would apply in those cases. *If licensees authorized for diagnostic use only are administering I-131 with activities greater than 30 microcuries for diagnostic studies, their licenses will now have to be amended to include 32 IAC 335.5010 "for diagnostic studies only."*
35.310	335.5020	**Safety Instruction** – Instructions now for attending staff only of patients not releasable under 32 IAC 335.2110. Reference to in-patient instruction now deleted. Reference to 32 IAC 400.120 included in addition to the training in this section.
35.315	335.5030	**Safety Precautions** – Precautions for housing patients that are not releasable under 32 IAC 335.2110 included here. Requirements for monitoring of patients room, bioassays and 48-hour holding period now deferred to 32 IAC 340.310, 32 IAC 340.320, 32 IAC 340.510 and 32 IAC 340.520.
		SUBPART G: SEALED SOURCES FOR DIAGNOSIS
35.500	335.6010	**Use of Sealed Sources for Diagnosis** - New language. Devices approved for use must be obtained from an individual licensed pursuant to 32 IAC 335.30 and must appear in the national registry. Specific nuclides deleted.
		SUBPART H: MANUAL BRACHYTHERAPY
35.400	335.7010	**Use of Sealed Sources for Manual Brachytherapy** - New language. Sources and devices approved for use must be obtained from an individual licensed pursuant to 32 IAC 335.30 and must appear in the national registry or meet FDA protocol for therapy devices.
35.410	335.7020	**Safety Instruction** - New language for safety instruction now for attending staff only for patients not releasable under 32 IAC 335.2110. Similar to old language.

35.415	335.7030	**Safety Precautions** - Added language here for emergency retrieval of sources. Deleted monitoring of adjacent rooms. Specific afterloader information moved to Subpart I.
35.406	335.7040	**Accountability and Security of Brachytherapy Sources** - Added accountability and security language. Specific requirements for temporary and permanent implants. Licensees must also note requirements of 32 IAC 340.810 for inventories. Moved monitoring to 32 IAC 335.7060.
N/A	335.7050	**Discharge of Patients Treated With Temporary Implants** - Repealed. 32 IAC 335.2110 now covers patient release.
35.404	335.7060	**Monitoring After Source Implant and Removal** - Requirements for brachytherapy surveys effectively the same as previous 32 IAC 335.7040.
35.432	335.7070	**Calibration Measurements of Brachytherapy Sources** - Calibration of brachytherapy sources required in this section using an approved dosimetry system (calibrated in accordance with 32 IAC 335.8080). Source positioning accuracy with applicators must also be determined both using nationally approved protocols.
35.433	335.7080	**Decay of Brachytherapy Sources** - Decay of brachytherapy sources must be calculated by an authorized medical physicist or authorized user. This includes Sr-90 eye applicators.
35.457	335.7090	**Therapy-related Computer Systems for Manual Brachytherapy** - New quality assurance requirements added for manual brachytherapy treatment planning systems.
		SUBPART I: REMOTE AFTERLOADER UNITS, INTRAVASCULAR BRACHYTHERAPY UNITS, TELETHERAPY UNITS AND GAMMA STEREOTACTIC RADIOSURGERY UNITS
	Summary	Remote Afterloaders, Intravascular Brachytherapy, Teletherapy and Gamma Stereotactic Radiosurgery Units put into one subpart. Most conditions of use and technical requirements formerly specified in radioactive materials licenses are now in this regulation. Emergency source retrieval and shielding of areas specified for each discipline. Annual training and emergency procedures drills for these uses are included. Quality assurance for remote systems are required. Calibration of units to be done in accordance with nationally recognized standards.

35.600	335.8010	**Use of a Sealed Source in a Remote Afterloader Unit, Intravascular Brachytherapy Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit** - New language. Devices approved for use must be obtained from an individual licensed pursuant to 32 IAC 335.30 and must appear in the national registry or meet an FDA approved IDE for research for therapy devices.
35.605	335.8020	**Installation, Maintenance, Adjustment, and Repair** - Installation/maintenance requirements for remote afterloader unit, intravascular brachytherapy unit, teletherapy unit, or gamma stereotactic radiosurgery unit. Similar to our standard license conditions and previous regulations for teletherapy.
N/A	335.8030	**Amendments to Teletherapy Licenses** – Provisions are still effective now addressed in 32 IAC 335.40.
35.610	335.8040	**Safety Procedures and Instructions for Remote Afterloader Units, Intravascular Brachytherapy Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units** - New safety procedures for all modalities. Prevents dual operation of units and provides for annual training and emergency procedures/drills among others.
35.615	335.8050	**Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units** - Similar safety precautions to previous teletherapy requirements now for all modalities. Added staff required to be present, emergency procedures/equipment. Requirements for area monitors, intercom and viewing systems are present here as well. Requirement for the physical presence of the authorized user and authorized medical physicist during gamma stereotactic treatments is included.
35.630	335.8060	**Radiation Monitoring Device for Teletherapy and Gamma Stereotactic Radiosurgery Units** – Details about area monitors are same as before but now include gamma stereotactic units.
N/A	335.8070	**Viewing System for Teletherapy** – This requirement is still effective but now is in 32 IAC 335.8050
35.630	335.8080	**Dosimetry Equipment** – Dosimetry equipment for teletherapy virtually the same as before but now expanded to include all modalities.
35.632	335.8090	**Full Calibration Measurements for Teletherapy** – Full calibration requirements for teletherapy similar to previous standards. Can now use nationally accepted protocols for full calibrations. *Licensees must make amendment requests for use of protocols other than those in previous commitments.*
35.642	335.8100	**Periodic Spot-Checks for Teletherapy** – Spot checks virtually the same as before. Item (g) added. This was formerly a license condition for locking out the unit if a malfunction occurs.

35.652	335.8110	**Radiation Monitoring** – New radiation monitoring section now refers to the Sealed Source and Device Registry sheet for radiation levels on therapy treatment devices.
N/A	335.8120	**Safety Checks for Teletherapy Facilities** – Requirements are still effective but now in 32 IAC 335.8100, 8170, 8190, 8200 and 8210.
N/A	335.8130	**Modification of Teletherapy Unit or Room Before Beginning a Treatment Program** – Requirements for amendments now in 32 IAC 335.40.
N/A	335.8140	**Reports of Teletherapy Monitoring, Checks, Tests and Measurements** – Deleted requirement to submit reports to the Agency. Records must be maintained for inspection in accordance with the applicable requirements of each section.
35.655	335.8150	**5-Year Teletherapy and Gamma Stereotactic Unit Inspections** – Similar 5-year inspection of units as in the past. Slightly different records content.
35.633	335.8160	**Full Calibration Measurements on Remote Afterloader Units** – Full calibration requirements for afterloaders similar to previous license commitments. Can now use nationally accepted protocols for full calibrations. *Licensees must make amendment request for use of protocols and calibration frequencies specified in the rule if other than those in previous commitments.*
35.643	335.8170	**Periodic Spot-Checks for Remote Afterloader Units** – Periodic spot-check requirements for afterloaders similar to previous license commitments. *Licensees must make amendment request for use of protocols and calibration frequencies specified in the rule if other than those in previous commitments.*
35.404	335.8180	**Monitoring of Patients and Human Research Subjects Treated with a Remote Afterloader Unit or Intravascular Brachytherapy Unit** – NRC language for surveys of patient for remote afterloader units. Similar to our previous 32 IAC 335.7040. Patients must still be surveyed following use of remote afterloaders.
35.635	335.8190-335.8200	**Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units and Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units** – Full calibrations/spot checks for gamma stereotactic units are now consistent with teletherapy unit requirements.
35.2647	335.8210	**Additional Technical Requirements for Mobile Remote Afterloader Units** – New requirements for mobile afterloader units. See 32 IAC 340.510(c) for survey instrument checks. *Amendments will be required for procedures other than those in previous commitments.*

N/A	335.8220	**Additional Technical Requirements for Intravascular Brachytherapy Units** – New requirements for IVB. These requirements were formerly required by license amendments. *Amendments will be required for procedures other than those in previous commitments.*
35.657 35.457	335.8230	**Therapy-related Computer Systems for Remote Afterloader Units, Intravascular Brachytherapy Units, Teletherapy Units and Gamma Stereotactic Units** – Quality Assurance requirements added for treatment planning systems and software for these modalities.
		SUBPART J: TRAINING AND EXPERIENCE REQUIREMENTS
		This subpart is unchanged from previous version of Part 32 IAC 335. However, didactic hours for physician training will be put back into 32 IAC 335 at the next opportunity due to NRC compatibility requirements.

- Section 32 IAC 335.9190 Resolution of Conflicting Requirements During Transition Period

  If this Part conflicts with the licensee's radiation safety program as identified in its license, this Part shall apply, unless the statements, representations, conditions and procedures in the license are more restrictive. However, if that licensee exercises its privilege to amend its license, the portion amended must comply with the requirements of this Part.